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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,669	08/16/2001	Masahiro Sakanaka	56238(71526)	4547

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EXAMINER	
KHARE, DEVESH	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,669	SAKANAKA ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-36,38-41,52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36, 38-41, 52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and remarks filed on 04/10/2006 are acknowledged. Claim 32 has been amended. Claims 42-44 have been cancelled. Claims 1-31,37 and 45-51 were earlier cancelled.

The rejection under 35 U.S.C. 112, second paragraph and first paragraph to comply with the written requirement of the Office Action mailed on 11/09/ 2005, have been withdrawn by the examiner in response to the applicants' amendments.

Claims 32-36, 38-41, 52 and 53 are currently pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 32-36, 38-41, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakanaka et al. (Sakanaka) (Jpn. J. Pharmacol. 67, Suppl. I, 297 P,1995) in combination with Liu (U.S. Patent 4,708,949) in view of Zhang et al. (Zhang) (Acta Pharmacologica Sinica 17(1), 44-48, 1996 Jan.) of record.

Sakanaka teaches red ginseng powder containing ginseng saponins and ginsenoside Rb_1 prevented "ischemia-induced learning disability and rescued ischemic hippocampus CA1 neurons in gebils (see Abstract, P 297).

While the Sakanaka teaches that ginsenoside Rb_1 is one of the neuroprotective molecules within ginseng root, which can be administered by intraperitoneal injections,

Sakanaka differs from applicant's method in that Sakanaka does not suggest the effective concentrations of ginsenoside Rb_1.

Liu teaches in abstract the therapeutic compositions composed of four plant extracts: ginsenoside, tetramethyl pyrazine, astragalan and atractylol. This therapeutic composition is highly effective in treating cerebral vascular diseases (also see claims 1-4). In claims 13-17, Liu teaches the method of treating a patient suffering from cerebrovascular disease and impaired neurofunction with a pharmaceutical composition comprising ginsenoside.

Zhang teaches the influences of ginsenosides Rb_1 and Rg_1 on the brains against ischemia-reperfusion injury (page 44, see AIM). Zhang discloses that ginsenosides such as Rb_1 from Panax ginseng protected rat brains from cerebral infarction (p. 44, 1st para.). Zhang discloses the effects of ginsenoside Rb_1 in rat model when used in the concentration of 10 mg- 40 mg/kg (pp. 46-47, Tables 1-3). Zhang also discloses the effects of Rb_1 on neurologic deficit in rats (Table 1 on page 46). Zhang discloses that "Rb_1 can reduce intracellular calcium while the calcium entry into cells is the final common pathway leading to cell death" (page 45, Ist col. Ist para.).

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). See MPEP 2144.05 part II A. Variance of dosage amounts with regard to known pharmaceutically active ingredients was well known in the art. One of ordinary skill in the art would have been motivated to modify the dosage amounts of ginsenoside Rb_1 in order to enable the

treatment protocol to be matched with the demands and needs of individuals who needed treatment. Such variations are considered optimization of results effective variables, conventional practice in the art of pharmacology.

Therefore, one of ordinary skill in the art would have found the applicants claimed method of treating a patient suffering from a traumatic or compression injury of a nervous tissue by administering to said patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb_1 to have been obvious at the time the invention was made having the above references before him because Sakanaka and Liu teach that ginsenoside Rb_1 from plant source is to prevent "ischemia-induced learning disability and rescued ischemic hippocampus CA1 neurons in gebils" and of treating a patient suffering from cerebrovascular disease; and Zhang teaches effective concentrations of ginsenoside Rb_1 in protecting rat brains from cerebral infarction. The motivation for doing so is provided by Sakanaka, which suggests ginsenoside Rb_1 is a neuroprotective molecule (p 297, last line).

Response to Arguments

Applicant's remarks filed on 04/10/2006 traversing the rejections of claims 32-36, 38-41, 52 and 53 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Applicants argue, "Zhang in combination with Sakanaka reference does not teach or suggest that ginsenoside Rb_1 can be used to treat a traumatic or compression injury of a nervous tissue."

The cited references Sakanaka in combination with Liu in view of Zhang disclose that ginsenoside Rb_1 is a neuroprotective molecule. Zhang teaches the influences of ginsenosides Rb_1 and Rg_1 on the brains against ischemia-reperfusion injury (page 44, see AIM). Furthermore, the Zhang reference also discloses that "Rb_1 can reduce intracellular calcium while the calcium entry into cells is the final common pathway leading to cell death" (page 45, Ist col. Ist para.). In the instant case, the use of a composition comprising a therapeutic agent Rb_1 in the treatment of a patient suffering from a traumatic or compression injury of a nervous tissue, would be considered an inherent property of ginsenoside Rb_1 which can be administered to a patient suffering from a traumatic or compression injuries to the nervous tissues. In the absence of unexpected results, it appears to be a compound having neuroprotective properties such as ginsenoside Rb_1 can be used to treat a patient suffering from a traumatic or compression injury of a nervous tissue.

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
June 19, 2006

6/20/06

Anna Jiang, Ph.D.
Supervisory Patent Examiner
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